IN THE IOWA DISTRICT COURT FOR POLK COUNTY

THE STATE OF IOWA, ex rel. THOMAS J. MILLER, ATTORNEY GENERAL 99AG25112	)	
Plaintiff,	)	
v.	)	**Equity No.** 68028
ASTRAZENECA PHAMACEUTICALS L.P.	)	
and	)	
ASTRAZENECA LP	)	
Defendants.	)	

FINAL JUDGMENT AND CONSENT DECREE

Plaintiff, the State of Iowa ex rel. Attorney General Thomas J. Miller, by Special Assistant Attorney General William L. Brauch, has filed a Petition for a permanent injunction and other relief in this matter pursuant to the Iowa Consumer Fraud Act, Iowa Code section 714.16, alleging that AstraZeneca Pharmaceuticals LP and AstraZeneca LP committed violations of the aforementioned Act.

Plaintiff, by its counsel, and AstraZeneca Pharmaceuticals LP and AstraZeneca LP, by their counsel, have agreed to the entry of this Final Judgment and Consent Decree ("Judgment") by the Court without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind.

PARTIES

1. The State of Iowa ex rel. Attorney General Thomas J. Miller, (hereinafter "the State"), is the plaintiff in this case. The Iowa Attorney General is charged with, among other things, the responsibility of enforcing the Consumer Fraud Act.

2. AstraZeneca Pharmaceuticals LP and AstraZeneca LP (hereinafter "AstraZeneca") are the Defendants in this case. AstraZeneca's Corporate Headquarters is located at, 1800 Concord Pike, Wilmington, DE 19850-5437. As used herein, any reference to "AstraZeneca" shall mean AstraZeneca Pharmaceuticals LP and AstraZeneca LP.

VENUE

AstraZeneca, at all times relevant hereto, engaged in the advertisement and sale of merchandise within the meaning of the Consumer Fraud Act, in the State of Iowa, including, but not limited to, Polk County.

PREAMBLE

A. The Attorneys General of thirty seven[1] states and the District of Columbia (collectively, the "Attorneys General," and the "AGs")[2], conducted an investigation regarding certain AstraZeneca practices concerning Seroquel.

B. The Parties have agreed to resolve the claims raised by the Covered Conduct, as set forth in Section VII, by entering into this Judgment. This Judgment is entered into pursuant to and subject to the State consumer protection laws[3] cited in footnote 3.

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[1] Arizona, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.

[2] Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity, the entire group will be referred to as the "Attorneys General," and such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection."

[3] ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; CALIFORNIA – Bus. & Prof Code §§ 17200 *et seq.* and 17500 *et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*; CONNECTICUT – *Connecticut Unfair Trade Practices Act*, Conn. Gen. Stat. §§ 42-110a *et seq.*; DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, *District of Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.201 *et. seq.*; HAWAII – *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. 501.201 *et seq.*; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 *et seq.*; ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; IOWA – *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KANSAS - *Kansas Consumer Protection Act*, K.S.A. 50-623 et seq.; LOUISIANA – *Unfair Trade-Practices and Consumer Protection Law*, LSA-R.S. 51:1401, *et seq.*; MAINE – *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MARYLAND - *Maryland Consumer Protection Act*, Md. Code Ann., Com. Law §§ 13-101 *et seq.*; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MINNESOTA - Minnesota Deceptive Trade Practices Act, Minn. Stat. §§ 325D.43-48; Minnesota False Advertising Act, Minn. Stat. § 325F.67; Minnesota Consumer Fraud Act, Minn. Stat. §§ 325F.68-70; Minnesota Deceptive Trade Practices Against Senior Citizens or Disabled Persons Act, Minn. Stat. § 325F.71.; MISSOURI – *Missouri Merchandising Practices Act*, Mo. Rev. Stat. §§ 407 et seq.;

C. AstraZeneca is entering into this Judgment solely for the purpose of settlement and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing (including allegations of the Petition), all of which AstraZeneca expressly denies. AstraZeneca does not admit any violation of law, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by AstraZeneca. This Judgment is made without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind. It is the intent of the Parties that this Judgment shall not be binding or admissible in any other matter, including, but not limited to, any investigation or litigation, other than in connection with the enforcement of this Judgment. No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment. To the extent that any provision of this Judgment obligates AstraZeneca to change any policy(ies) or procedure(s) and to the extent not already accomplished, AstraZeneca shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the Effective Date of this Judgment. Nothing

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NEBRASKA – *Uniform Deceptive Trade Practices Act*, NRS §§ 87-301 *et seq.*; NEVADA – Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW HAMPSHIRE – *New Hampshire Consumer Protection Act*, RSA 358-A; NEW JERSEY – *New Jersey Consumer Fraud Act*, NJSA 56:8-1 *et seq.*; NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1.1, *et seq.*; NORTH DAKOTA – *Unlawful Sales or Advertising Practices*, N.D. Cent. Code § 51-15-02 *et seq.*; OHIO – *Ohio Consumer Sales Practices Act*, R.C. 1345.01, *et seq.*; OKLAHOMA - Oklahoma Consumer Protection Act 15 O.S. §§ 751 *et seq.*; OREGON -- Oregon Unlawful Trade Practices Act, ORS 646.605 *et seq.*; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 *et seq.*; RHODE ISLAND - Rhode Island Deceptive Trade Practices Act, Rhode Island General Laws § 6-13.1-1, *et seq.*; SOUTH DAKOTA – *South Dakota Deceptive Trade Practices and Consumer Protection*, SDCL ch. 37-24; TENNESSEE – *Tennessee Consumer Protection Act*, Tenn. Code Ann. 47-18-101 *et seq.*; TEXAS – *Texas Deceptive Trade Practices-Consumer Protection Act*, Tex. Bus. And Com. Code 17.47, *et seq.*; VERMONT – *Consumer Fraud Act*, 9 V.S.A. §§ 2451 *et seq.*; WASHINGTON – *Unfair Business Practices/Consumer Protection Act*, RCW §§ 19.86 *et seq.*; WEST VIRGINIA – *West Virginia Consumer Credit and Protection Act*, W. Va. Code § 46A-1101 *et seq.*; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

contained herein prevents or prohibits the use of this Judgment for purposes of enforcement by the AGs.

D. This Judgment does not create a waiver or limit AstraZeneca's legal rights, remedies, or defenses in any other action by the Signatory Attorney General, and does not waive or limit AstraZeneca's right to defend itself from, or make argument in, any other matter, claim, or suit, including, but not limited to any investigation or litigation relating to the existence, subject matter, or terms of this Judgment. Nothing in this Judgment shall waive, release, or otherwise affect any claims, defense, or positions AstraZeneca may have in connection with any investigations, claims, or other matters the State is not releasing hereunder.

E. The AGs have reviewed the terms of the Judgment and find that its entry serves the public interest.

IT IS HEREBY ORDERED that:

DEFINITIONS

The following definitions shall be used in construing this Judgment:

1. "AstraZeneca" shall mean "AstraZeneca Pharmaceuticals LP" and "AstraZeneca LP," including all of their subsidiaries, divisions, successors, and assigns doing business in the United States.

2. "AstraZeneca's Legal Department" shall mean personnel of the AstraZeneca Legal Department or its designee providing legal advice to AstraZeneca.

3. "AstraZeneca Marketing" shall mean AstraZeneca commercial personnel assigned to the U.S. Seroquel brand team.

4. "AstraZeneca Medical Education Grants Office" and "MEGO" shall mean the U.S.-based organization within AstraZeneca responsible for oversight of medical education grants and the acceptance, review, and payment of all medical education grant requests.

5. "AstraZeneca Non-SciP" shall mean AstraZeneca personnel other than AstraZeneca Scientifically Trained Personnel or SciP.

6. "AstraZeneca Sales" shall mean the AstraZeneca pharmaceutical sales specialists, or other AstraZeneca personnel, responsible for U.S. Seroquel sales.

7. "AstraZeneca Scientifically Trained Personnel" or "SciP" shall mean AstraZeneca personnel who are highly trained experts with specialized scientific and medical knowledge whose roles involve the provision of specialized medical or scientific information, but excludes anyone performing sales, marketing, ride alongs, or other commercial roles.

8. "Clinically Relevant Information" shall mean information that reasonably prudent clinicians would consider relevant when making prescribing decisions regarding Seroquel.

9. "Consultant" shall mean a non-AstraZeneca Health Care Professional engaged to advise regarding marketing or promotion of Seroquel.

10. "Covered Conduct" shall mean AstraZeneca's Promotional and marketing practices, sampling practices, dissemination of information (including clinical research results), and remuneration to Health Care Professionals, in connection with Seroquel through the Effective Date of the Judgment.

11. "Effective Date" shall mean the date on which a copy of this Judgment, duly executed by AstraZeneca and by the Signatory Attorney General, is approved by, and becomes a Judgment of the Court.

12. "FDA Guidances for Industry" shall mean draft or final documents published by the United States Department of Health and Human Services, Food and Drug Administration ("FDA") that represent the FDA's current thinking on a topic.

13. "Health Care Professional" or "HCP" shall mean any physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical products in the United States.

14. "Labeling" shall mean all FDA-approved labels, which are a display of written, printed, or graphic matter upon the immediate container of any article, and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

15. "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing Arizona, Delaware, District of Columbia, Florida, Illinois, Kansas, Maryland, Massachusetts, North Carolina, Ohio, Pennsylvania, and Vermont.

16. "Multistate Working Group" shall mean the Attorneys General and their staff representing Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.

17. "Off-Label" shall mean a use not consistent with the indications section of the Seroquel Labeling approved by the FDA at the time information regarding such use was communicated.

18. "Parties" shall mean AstraZeneca and the Signatory Attorney General.

19. "Professional Information Request Response" or "PIR Response" shall mean a non-promotional, scientific or reference communication to address Unsolicited Requests for medical information from HCPs.

20. "Promotional," "Promoting" or "Promote" shall mean representations made to HCPs, patients, consumers, payers and other customers and other practices intended to increase sales or that attempt to influence prescribing practices of HCPs.

21. "Promotional Slide Deck" shall mean Promotional materials in any medium regarding Seroquel for use in speaker programs in the United States.

22. "Promotional Speaker" shall mean a HCP speaker engaged to Promote Seroquel in the United States.

23. "Reprints Containing Off-Label Information" shall mean articles or reprints from a Scientific or Medical Journal, as defined in 21 C.F.R. 99.3(j), or Reference Publication, as defined in 21 C.F.R. 99.3(i), describing an Off-Label use of Seroquel.

24. "Seroquel" shall mean all FDA-approved drug formulations containing quetiapine fumarate as its principal active ingredient and Promoted by AstraZeneca in the United States, including Seroquel XR.

25. "Signatory Attorney General" shall mean the Attorney General of Iowa, or his authorized designee, who has agreed to this Judgment.

26. "Unsolicited Request" shall mean a request for information regarding Seroquel from a HCP communicated to an agent of AstraZeneca that has not been prompted by AstraZeneca.

COMPLIANCE PROVISIONS

Except for Sections I.A-C, I.E-G, II.A; II.D.1, IV, and V below, the Compliance Provisions shall apply for six (6) years from the Effective Date of this Judgment.

I. Promotional Activities

A. AstraZeneca shall not make any written or oral claim that is false, misleading or deceptive regarding Seroquel.

B. AstraZeneca shall not Promote Seroquel for Off-Label uses.

C. In Promotional materials for Seroquel, AstraZeneca shall clearly and conspicuously disclose the risks associated with the product as set forth in the product's black box warning and shall present information about effectiveness and risk in a balanced manner.

D. AstraZeneca shall not present patient profiles/types based on selected symptoms of the FDA-approved indication(s) when Promoting Seroquel, unless:

1. The drug's specific FDA-approved indication(s) is/are stated clearly and conspicuously in the same spread (*i.e.,* on the same page or on a facing page) in any Promotional materials that refer to selected symptoms.

a. With respect to Promotional Slide Decks:

(i) AstraZeneca shall state clearly and conspicuously the FDA-approved indication(s) on the same slide in which selected symptoms are first presented;

(ii) AstraZeneca shall include a short-hand reference to the statement described in Section I.D.1.a.(i) on the same slide as each subsequent reference to selected symptoms (*e.g.,* "Seroquel is not approved for X selected symptom

referenced in this slide. See list of FDA-approved indications at p. Y"); and,

(iii) AstraZeneca shall require any presenter of AstraZeneca's Promotional Slide Decks to present the statement required in Section I.D.1.a.(i), as part of the mandatory slides.

2. Promotional materials have a reference indicating that the full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV or current version), where applicable.

E. AstraZeneca shall ensure that all Promotional Speakers' Promotional materials for Seroquel comply with AstraZeneca's obligations in the above Sections I.A–D.

F. AstraZeneca's systems and controls shall 1) be designed to ensure that financial incentives do not motivate AstraZeneca Marketing and/or Sales personnel to engage in improper promotion, sales, and marketing of Seroquel; and 2) include mechanisms to exclude from incentive compensation sales that may indicate Off-Label promotion of Seroquel.

G. AstraZeneca's systems and controls shall be designed to prevent AstraZeneca Sales from detailing Seroquel to HCPs who are unlikely to prescribe Seroquel for a use consistent with its FDA-approved label. This shall be effected through systems and controls requiring that AstraZeneca review the call plans for Seroquel and the bases upon, and circumstances under which HCPs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call plans. The systems and controls shall require that AstraZeneca modify the call plans as necessary to ensure that AstraZeneca is

Promoting Seroquel in a manner that complies with applicable Federal health care program and FDA requirements.

H. AstraZeneca's detailing systems and its controls shall prevent the delivery of samples of Seroquel to HCPs that AstraZeneca has identified as belonging to a specialty group that is unlikely to prescribe Seroquel for a use consistent with its FDA-approved label.

II. Dissemination and Exchange of Medical Information

A. General Terms

1. The content of AstraZeneca's communications concerning Off-Label uses of Seroquel shall not be false, misleading or deceptive.

B. Professional Information Request Responses

1. AstraZeneca Scientifically Trained Personnel shall have ultimate responsibility for developing and approving the medical content for all PIR Responses regarding Seroquel, including any that may describe Off-Label information. AstraZeneca shall not distribute any such materials unless:

   a. Clinically Relevant Information is included in these materials to provide scientific balance;

   b. Data in these materials are presented in an unbiased, non-Promotional manner; and

   c. These materials are distinguishable from sales aids and other Promotional materials.

2. AstraZeneca Sales and AstraZeneca Marketing personnel shall not develop the medical content of PIR Responses regarding Seroquel.

3. AstraZeneca Sales representatives shall not distribute PIR Responses regarding Seroquel unless specifically authorized to do so pursuant to II.C.6.

4. AstraZeneca shall not knowingly disseminate any PIR Response describing any Off-Label use of Seroquel that makes any false, misleading or deceptive representation regarding Seroquel or any false or misleading or deceptive statement concerning a competing product.

C. Responses to Unsolicited Requests for Off-Label information

1. In responding to an Unsolicited Request for Off-Label information regarding Seroquel, including any request for a specific article related to Off-Label uses, AstraZeneca shall advise the requestor that the request concerns an Off-Label use and inform the requestor of the drug's FDA-approved indication(s), dosage and other relevant Labeling information.

2. If AstraZeneca elects to respond to an Unsolicited Request for Off-Label information from a HCP regarding Seroquel, AstraZeneca Scientifically Trained Personnel shall provide accurate, objective, and scientifically balanced responses. Any such response shall not Promote Seroquel for an Off-Label use.

3. Any written response to an Unsolicited Request for Off-Label information made to AstraZeneca Sales or AstraZeneca Marketing regarding Seroquel shall include:

a. an existing PIR Response prepared in accordance with Section II.B;

b. a PIR Response prepared in response to the request in accordance with Section II.B; or

c. a report containing the results of a reasonable literature search using terms from the request.

4. Only AstraZeneca Scientifically Trained Personnel may respond in writing to an Unsolicited Request for Off-Label information regarding Seroquel unless AstraZeneca Non-SciP are specifically authorized to do so pursuant to II.C.6.

5. AstraZeneca Non-SciP may respond orally to an Unsolicited Request for Off-Label information regarding Seroquel from a HCP only by offering to request on behalf of the HCP that a PIR Response or other information set forth above in II.C.3 be sent to the HCP in follow up or by offering to put the HCP in touch with the Virtual Scientific Exchange Center ("VSEC"). AstraZeneca Non-SciP shall not characterize, describe, identify, name, or offer any opinions about or summarize any Off-Label information.

6. PIR Responses regarding Seroquel may be disseminated only by AstraZeneca Scientifically Trained Personnel to HCPs, and AstraZeneca Non-SciP shall not disseminate these materials to HCPs except in circumstances implicating public health and safety issues. In such circumstances, AstraZeneca Non-SciP may disseminate a PIR Response directly to HCPs, when expressly authorized by the U.S. Compliance Officer, the U.S. General Counsel, and the Vice President of Medical Affairs.

D. Reprints

1. AstraZeneca shall not disseminate information or written materials describing Off-Label or unapproved uses of Seroquel unless such information and materials comply with applicable FDA regulations and FDA Guidance for Industry;

2. Reprints Containing Off-Label Information

a. AstraZeneca Scientifically Trained Personnel shall be responsible for the identification, selection, approval and dissemination of Reprints Containing Off-Label Information regarding Seroquel.

b. Requests to proactively disseminate a Reprint Containing Off-Label Information shall be submitted to the appropriate director of Medical Affairs, who will convene a cross-functional team, including a representative from Clinical, Medical Affairs, AstraZeneca's U.S. Compliance Department, AstraZeneca's Legal Department, and Promotional Regulatory Affairs, to examine the facts and justification for the request to distribute a Reprint Containing Off-Label Information on a case-by-case basis.

c. Reprints Containing Off-Label Information shall:

   (i) be accompanied by the full prescribing information for the product, or a clearly and conspicuously described hyperlink that will provide the reader with such information, and contain a disclosure in a prominent location, which would include the first page or as a cover page where practicable, indicating that the article may discuss Off-Label information; and

   (ii) not be referred to or used in a Promotional manner.

d. Reprints Containing Off-Label Information regarding Seroquel may be disseminated only by AstraZeneca Scientifically Trained

Personnel to HCPs. AstraZeneca Non-SciP shall not disseminate these materials to HCPs.

3. Nothing in this Judgment shall preclude AstraZeneca from disseminating Reprints which have an incidental reference to Off-Label information. If Reprints have an incidental reference to Off-Label information, such reprints shall contain the disclosure required by section II.D.2.c.(i) in a prominent location, as defined above, and such incidental reference to Off-Label information shall not be referred to or used in a Promotional manner as prohibited by Section II.D.2.c.(ii).

III. Grants

A. AstraZeneca shall disclose information about medical education grants, including CME grants, regarding Seroquel consistent with the current disclosures of MEGO with a link to the disclosures available through AstraZeneca's website and as required by applicable law.

1. AstraZeneca shall maintain this information on the website, once posted, for at least two years, or longer if applicable law so requires, and shall maintain the information in a readily accessible format for review by the States upon written request for a period of five years.

B. MEGO shall manage all requests to AstraZeneca for funding related to medical education grants regarding Seroquel. Approval decisions shall be made by MEGO alone, and shall be kept separate from the AstraZeneca Sales and AstraZeneca Marketing organizations.

C. AstraZeneca shall not use medical education grants or any other type of grant to Promote Seroquel. This provision includes, but is not limited to, the following prohibitions:

1. AstraZeneca Sales and AstraZeneca Marketing personnel shall not initiate, coordinate or implement grant applications on behalf of any customer or HCP;

2. AstraZeneca Sales and AstraZeneca Marketing personnel shall not be involved in selecting grantees or medical education speakers; and

3. AstraZeneca shall not measure or attempt to track in any way the impact of grants or speaking fees on the participating HCPs' subsequent prescribing habits, practices or patterns.

D. AstraZeneca shall not condition funding of a medical education program grant request relating to Seroquel upon the requestor's selection or rejection of particular speakers.

E. AstraZeneca shall not suggest, control, or attempt to influence selection of the specific topic, title, content, speakers or audience for CMEs relating to Seroquel, consistent with Accreditation Council for Continuing Medical Education Guidelines.

F. AstraZeneca Sales and AstraZeneca Marketing personnel shall not approve grant requests relating to Seroquel, nor attempt to influence the awarding of grants to any customers or HCPs for their prescribing habits, practices or patterns.

G. AstraZeneca shall contractually require the medical education provider to clearly and conspicuously disclose to medical education program attendees AstraZeneca's financial support of the medical education program and any financial relationship with faculty and speakers at such medical education program.

H. After the initial delivery of a medical education program, AstraZeneca shall not knowingly fund the same program, nor shall it provide additional funding for re-distribution of the same program, if the program's speakers are Promoting Seroquel for Off-Label uses in that program.

IV. Payments to Consultants and Speakers

A. This Section shall be effective for five (5) years from the Effective Date of this Judgment and shall apply to U.S. based Consultants and Promotional Speakers performing Promotional activities for AstraZeneca.

B. Phase I Reporting.

1. AstraZeneca shall continue to post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below in Section IV.D.5) who or which received Phase I Payments (as defined below in Section IV.D.2) directly or indirectly from AstraZeneca during the first six months of 2010 and the aggregate value of such Phase I Payments.

2. On or before February 28, 2011, AstraZeneca shall also post on its website a listing of updated information about all Phase I Payments provided during the last six months of 2010. On or before May 31, 2011, AstraZeneca shall also post on its website a listing of updated information about all Phase I Payments provided during the first quarter of 2011. On or before June 30, 2011, AstraZeneca shall also post on its website a report of the cumulative value of the Phase I Payments provided to each physician, and/or Related Entity during 2010. The quarterly, six-month, and annual reports shall be easily accessible and readily searchable.

3. Each listing made pursuant to this Section IV. B shall include a complete list of all individual physicians and Related Entities to whom or to which AstraZeneca directly or indirectly made Payments in the preceding six-month period, quarter, or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or the name of the Related Entity. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and

state that the physician or Related Entity has provided to AstraZeneca for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter, six-month period, or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

C. Phase II Reporting

1. On or before August 31, 2011, AstraZeneca shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Phase II Payments (as defined below in Section IV.D.3) directly or indirectly from AstraZeneca during the second quarter of 2011 and the aggregate value of such Phase II Payments.

2. After the August 31, 2011 posting, 30 days after the end of each subsequent calendar quarter, AstraZeneca shall post on its website a listing of updated information about all Phase II Payments provided from the first reporting quarter of the year through the close of the most recent quarter of the year. Beginning in 2012, on or before May 1 of each year, AstraZeneca shall also post on its website a report of the cumulative value of the Phase II Payments provided to each physician, and/or Related Entity during each preceding calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

D. Definitions and Miscellaneous Provisions

1. AstraZeneca shall continue to make each annual listing and the most recent six-month or quarterly listing of Payments available on its website. AstraZeneca shall retain and make available to each Signatory Attorney General, upon request, relevant business records sufficient to demonstrate the purpose of the Payment and (where applicable) the performance of a service by the HCP related to all applicable Payments and to the annual, six-

month, and/or quarterly listings of Payments. Nothing in this Section IV affects the responsibility of AstraZeneca to comply with (or liability for noncompliance with) all applicable state laws as they relate to all applicable Payments made to physicians or Related Entities.

2. For purposes of Section IV.B, the term "Phase I Payments" is defined as all fees paid in connection with U.S.-based physicians serving as Promotional Speakers in the United States or participating in prerequisite speaker training for such Promotional Speaker engagements.

3. For purposes of Section IV.C, the term "Phase II Payments" is defined to include all Phase I Payments and all other "payments or transfers of value" as that term is defined in § 1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act ("PPACA") and any regulations promulgated thereunder. The term Phase II Payments includes, by way of example, the types of payments or transfers of value enumerated in § 1128G(a)(1)(A)(vi) of PPACA. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom AstraZeneca would otherwise report a Payment if made directly to the physician. The term "Phase II Payments" also includes any payments or transfers of value made, directly by AstraZeneca or by a vendor retained by AstraZeneca to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

4. The term "Payments" as used in the definition of Phase I Payments and Phase II Payments does not include transfers of value or other items that are not included or are excluded from the definition of "payment" as set forth in § 1128G(e)(10) under Section 6002 of PPACA and any regulations promulgated thereunder.

5. For purposes of this Section IV, the term "Related Entity" is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

E. Once the Federal Physician Payments Sunshine Act becomes effective, AstraZeneca shall comply with the Federal Physician Payments Sunshine Act, Section 6002 of the PPACA and it is agreed that AstraZeneca's compliance with the Physician Payment Sunshine Provision of PPACA will constitute compliance with Section IV of this Final Judgment and Consent Decree.

V. Clinical Research Results

A. AstraZeneca shall report clinical research regarding Seroquel in an accurate, objective and balanced manner as follows and as required by applicable law:

1. To the extent permitted by the National Library of Medicine and as required by the FDA Amendments Act of 2007 (Public Law No. 110-85), AstraZeneca shall register clinical trials and submit clinical trial results to the registry and results data bank regarding Seroquel as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act. With respect to Seroquel, AstraZeneca registers on a publicly accessible NIH website (www.clinicaltrials.gov) the initiation of all AstraZeneca-sponsored clinical studies involving individuals and posts a summary of the results of all AstraZeneca-sponsored clinical studies in patients or volunteers for marketed and investigative products on the above-referenced NIH website and on a company website (www.astrazenecaclinicaltrials.com).

B. When presenting information about a clinical study regarding Seroquel, AstraZeneca shall not do any of the following in a manner that causes the Promotional materials to be false, misleading or deceptive:

1. present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

2. use the concept of statistical significance to support a claim without providing the appropriate clinical context, or which fails to reveal the range of variations around the quoted average results;

3. use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations;

4. present the information in a way that implies that the study represents larger or more general experience with the drug than it actually does; or

5. use statistics on numbers of patients, or counts of favorable results or side effects, derived from pooling data, unless such pooling has been done in a statistically rigorous manner, pursuant to a protocol, and that the method of pooling has been disclosed.

PAYMENT AND RELEASE PROVISIONS

VI. Terms Relating to Payment

A. No later than 30 days after the Effective Date of this Judgment, AstraZeneca shall pay $68.5 million to be divided and paid by AstraZeneca directly to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. The Parties acknowledge that the payment described herein is not a fine or penalty, or payment in lieu thereof. The payment to the Attorney General of Iowa shall be used for the purposes referenced in Iowa Code section 714.16C.

VII. Release

A. By its execution of this Judgment, the State of Iowa releases and forever discharges AstraZeneca, and all of its past and present subsidiaries, divisions, affiliates, co-promoters, controlled joint ventures, predecessors, successors, and assigns and each and all of their current and former officers, directors, shareholders, employees, agents, contractors,and attorneys (collectively, the "Released Parties") of and from the following: all civil claims, causes of action, *parens patriae* claims, damages, restitution, fines, costs, attorneys fees, remedies and/or penalties that the Iowa Attorney General has asserted or could have asserted against the Released Parties under the Iowa Consumer Fraud Act or any amendment thereto, or common law claims concerning unfair, deceptive, or fraudulent trade practices resulting from the Covered Conduct up to and including the Effective Date (collectively, the "Released Claims").

B. Notwithstanding any term of this Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:

1. Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Iowa.

2. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Iowa not expressly covered by the release in Section VII.A above, including, but not limited to, any and all of the following claims:

a. State or federal antitrust violations;

b. Claims involving "best price," "average wholesale price" or "wholesale acquisition cost;"

c. Medicaid violations, including but not limited to federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any state's Medicaid program; and

d. State false claims violations.

3. Actions of state program payors of the State of Iowa arising from the purchase of Seroquel, except for the release of civil penalties under the state consumer protection laws cited in footnote 3.

4. Any claims individual consumers have or may have under the State of Iowa consumer protection laws against any person or entity, including Released Parties.

PROVISIONS RELATED TO OTHER LAWS AND DISPUTE RESOLUTION

VIII. Conflicts with Other Laws

A. This Judgment (or any portion thereof) shall in no way be construed to prohibit AstraZeneca from making representations with respect to Seroquel that are permitted under Federal law or in Labeling for the drug under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidances for Industry, or permitted or required under any Investigational New Drug Application, New Drug Application, Supplemental New Drug Application, or Abbreviated New Drug Application approved by FDA, unless facts are or become known to AstraZeneca that such representation, taken in its entirety, is false, misleading or deceptive. Nothing in this paragraph should be interpreted to excuse AstraZeneca from implementing any of the affirmative obligations described in the Compliance Provisions of this Judgment. If, subsequent to the Effective Date of this Judgment, the laws or regulations of the United States are changed so as to expressly authorize conduct that is expressly prohibited by this Judgment, then such conduct shall not constitute a violation of this judgment. Provided however, if AstraZeneca intends to engage in the expressly authorized conduct, AstraZeneca shall notify the Attorneys General (or the Attorney General of the affected state) within 30 business days prior to engaging in the expressly authorized conduct.

B. If, subsequent to the Effective Date of this Judgment, the federal government or any state, or any federal or state agency, enacts or promulgates legislation, regulations, or guidances with respect to matters governed by this Judgment that creates a conflict with any of the Compliance Provisions of the Judgment and AstraZeneca intends to comply with the newly enacted legislation, regulation, or guidance, AstraZeneca shall notify the Attorneys General (or the Attorney General of the affected State) of the same. If the Attorney General agrees, he/she

shall consent to a modification of such provision of the Judgment to the extent necessary to eliminate such conflict. If any Attorney General disagrees and the Parties are not able to resolve the disagreement, AstraZeneca shall seek a modification from an appropriate court of any provision of this Judgment that presents a conflict with any such federal or state law, regulation, or guidance. The disagreement of an Attorney General shall in no way impact AstraZeneca's ability to take action in any state and/or territory not represented by that Attorney General. Changes in federal or state laws, regulations, or guidances with respect to the matters governed by this Judgment shall not be deemed to create a conflict with a provision of this Judgment unless AstraZeneca cannot reasonably comply with both such law, regulation, or guidance and the applicable provision of this Judgment.

IX. Dispute Resolution

A. For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that AstraZeneca has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify AstraZeneca in writing of the specific objection, identify with particularity the provisions of this Judgment that the practice appears to violate, and give AstraZeneca thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action. Upon receipt of written notice, AstraZeneca shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why AstraZeneca believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and statement explaining how and when AstraZeneca intends to remedy the alleged violation. Nothing in this paragraph shall be interpreted to limit the State's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable state law, and AstraZeneca reserves all of its rights with respect to a CID or investigative subpoena issued pursuant to such authority.

B. Upon giving AstraZeneca thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody or control of AstraZeneca that relate to AstraZeneca's compliance with each provision of this Judgment as to which cause that is legally sufficient in the State has been shown.

C. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to AstraZeneca. Any and all documents and information (including, but not limited to, electronic information) provided in response to a request by the State shall be protected to the extent provided by the requesting State's Freedom of Information Act or other state law. Such documents or information shall not be disclosed by the State to any other party or entity (pursuant to a FOIA request, subpoena, or otherwise) without first providing notice to AstraZeneca, to the extent allowed by law, so that AstraZeneca may take necessary steps to protect its confidential documents or information prior to disclosure.

D. The State of Iowa may assert any claim that AstraZeneca has violated this Judgment in that State in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law, but only after providing AstraZeneca an opportunity to respond to the notification described in Paragraph IX.A. above, provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public of that State requires immediate action.

X. Timely Written Requests for Extensions

Nothing will prevent the State from agreeing in writing to provide AstraZeneca with additional time to perform any act or to file any notification required by the Judgment. The Attorney General shall not unreasonably withhold his/her agreement to the request for additional time.

XI. General Provisions

A. AstraZeneca shall not cause or encourage third parties, nor knowingly permit third parties acting on its behalf, to engage in practices from which AstraZeneca is prohibited by this Judgment.

B. This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, neither prior versions of this Judgment, nor prior versions of any of its terms, that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

C. This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

D. This Judgment may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

E. Defendant is liable for court costs, which are included in the payment to the State of Iowa pursuant to Section IV, paragraph A of this Judgment.

F. All Notices under this Judgment shall be provided to John C. Dodds and the U.S. Compliance Officer of AstraZeneca by Overnight Mail at:

John C. Dodds
Morgan, Lewis & Bockius LLP
1701 Market St.
Philadelphia, PA 19103

Marie L. Martino
U.S. Compliance Officer
AstraZeneca
1800 Concord Pike
PO Box 15437
Wilmington, DE 19850-5437

IT IS SO ORDERED, this 10th day of March 2011.

JUDGE, Fifth Judicial District

Copies served on all parties!
WJB 3-10-11

APPROVED:

PLAINTIFF, THE STATE OF IOWA

By: William L. Brauch Date: March 10, 2011

William L. Brauch,
Director - Consumer Protection Division
1305 E. Walnut Street
Des Moines, IA 50319
(515)281-8772
Bill.brauch@iowa.gov

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP

By: Marie L. Martino Date: 3/10/11

Marie L. Martino
U.S. Compliance Officer
AstraZeneca
1800 Concord Pike
PO Box 15437
Wilmington, DE 19850-5437

Approved as to form:

By: John C Dodds Date: 3/10/2011

John C. Dodds
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1701 Market St.
Philadelphia, PA 19103-2921
215.963.4942
215.963.5001-Fax
jdodds@morganlewis.com

Attorney for AstraZeneca Pharmaceuticals LP and AstraZeneca LP